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The use of a novel clinical decision support system for reducing medication errors and expediting care in the provision of chemotherapy

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Abstract

Background The clinical use of software, specifically clinical decision support systems (CDSS) coupled with computerized provider order entry (CPOE) systems (CPOE/CDSS), has strong potential to improve chemotherapy treatment.

Objective The aim of this observational study was to evaluate whether the use of a CPOE/CDSS in chemotherapy treatment can improve dosing accuracy and/or expedite the patient intake process.

Setting/Method We conducted a month-long pilot implementation of a proprietary CPOE/CDSS called CenseoRx® at a large hospital in Athens, Greece. Anonymized chemotherapy dosage data, patient intake time, and time to log laboratory exams were recorded from 58 subjects.

Main outcome measure The therapeutic dosing decisions of physicians and of the software were compared. The time required to admit a new patient and the time required to log laboratory exams were recorded on the first and last week of the study period and compared.

Results A significant difference between the doctor-prescribed and the CPOE/CDSS-recommended dosage of the chemotherapeutic agents was observed for medications requiring body surface area (BSA)-based dosing, area under the curve (AUC)-based dosing, or weight-based dosing [mean difference = 18.42 mg chemotherapeutic agent, $p = 0.0040$] and for medications requiring solely AUC-based dosing [mean difference = 95.62 mg chemotherapeutic agent, $p = 0.0295$], with doctors under-prescribing the chemotherapeutic drug as compared to the CPOE/CDSS. A significant decrease in time needed for patient intake and for logging laboratory results was observed over the study period [mean difference = 121.5 s; mean difference = 89.0 s, respectively].

Conclusions The implementation of a CPOE/CDSS can enhance the safety and quality of chemotherapy treatment.

Impacts on practice/Research summary

- Chemotherapeutic agents can lead to toxicity or therapeutic failure due to their narrow therapeutic index.
- The implementation of clinical decision support systems (CDSS) for the provision of chemotherapeutic agents can help to upgrade the chemotherapy prescribing process by reducing patient intake time.
- CDSSs coupled with computerized provider order entry systems (CPOEs) can help to facilitate a standardized and synergized clinical practice and ultimately reduce medication dosing errors.
- Clinical adoption of a CPOE/CDSS system can drive provider cost-savings by facilitating the utilization of leftover chemotherapeutic agents and by enhancing cross-silo communication to improve organizational efficiency.
- A CPOE/CDSS tool can prove didactic in medical education and training, especially in relation to oncological care and chemotherapy prescription dosing.

Keywords Clinical decision support systems · CDSS · Homogeneous clinical practice · Computerized provider order entry system · CPOE · CPOE/CDSS · Chemotherapy · Medication errors · Dosing errors · Oncology care · Clinical pharmacy · Electronic medicine · E-medicine

Extended author information available on the last page of the article

Abbreviations

CDSS	Clinical Decision Support System.
CPOE	Computerized Order-Entry System.
CPOE/CDSS	Combined Computerized Order-Entry and Clinical Decision Support System.
BSA	Body surface area dosing,
AUC	Area under the curve dosing.
WBC	White blood cell count.
ANC	Absolute neutrophil count.
LDH	Lactate dehydrogenase.
AST	Aspartate aminotransferase.
ALT	Alanine aminotransferase.
GGT	Gamma-glutamyl transferase.
ASHP	American Society of Health-System Pharmacists.

1 Background

During a typical chemotherapy treatment course for a variety of cancer types, the phases for clinical delivery of the chemotherapeutic agent are prescription, preparation, dispensation, and administration. From the clinician's standpoint, medication errors represent a potentially fatal risk when prescribing cytotoxic chemotherapeutic agents, and all phases of treatment delivery are amenable to error [1, 2]. However, most medication errors and fatal events associated with anticancer agents occur at the prescription phase, specifically during the dosage calculation [3, 4]. Inaccurate or imprecise dosage calculations, when coupled with the narrow therapeutic index of chemotherapeutic agents, can often lead to over- or underdosing, with profound and potentially harmful clinical ramifications. Most prominently, these serious adverse effects are iatrogenic drug toxicity and therapeutic failure [5].

In Greece—the setting of the present study—a risk assessment of central chemotherapy preparation units concluded that instances of avoidable harm are frequent in the manufacture and packaging of sterile cytotoxic drug solutions [11]. Recent studies note that the most relevant problems in Greek public hospitals are frequent noncompliance with international drug manufacture standards, human errors in cytotoxic drug compounding, diluting, and reconstituting, mislabeling, and work protocol violations [11].

One way to mitigate dosage errors and to generally enhance the safety and the quality of chemotherapy-use process is by introducing electronic systems and procedures to facilitate the logistics of the chemotherapy process across all treatment phases. One such tool that is increasingly being implemented in clinical practice is a computerized provider order entry (CPOE) system coupled with clinical decision support systems (CDSSs) [6, 7]. This type of integrated hybrid electronic system is typically referred to

as a CPOE/CDSS, and these systems commonly interface with both prescribing physicians and their counterpart clinical pharmacists. The CPOE component of these software systems facilitate quick and accurate prescription ordering to compound pharmacies by prescribing physicians through a two-way software platform, while the CDSS component provides automated dosage and scheduling protocol recommendations to physician according to recent guidelines.

As evinced by the seminal research on the implementation of a computer-assisted biohazard safety cabinet for preparation of the mixture of anticancer agents by Okayasu et al. (2009), errors in anticancer agent amounts were much smaller and the time spent in preparation was significantly shorter in computer-assisted procedures than in human-led pharmaceutical prescribing and preparation [12]. Safe management in cancer chemotherapy is of paramount importance, and it is well established by previous work and their findings that computer-assisted chemotherapy treatment is safer, more accurate in dosing schedules, and faster than exclusively human-led treatment protocols [7].

As the direct successors of computer-assisted biohazard safety cabinets, modern CPOE/CDSSs used for the verification of prescription orders and accurate compound preparation typically have three core operating components: a standardization procedure, an automation procedure, and a prescription accuracy verification procedure. The standardization procedure facilitates correct and quick unit conversion and between prescriber and pharmacy. The automation procedure provides for software-calculated dosing to elide the stochasticity of human error. Several studies have found evidence that the automation of dosing calculations requiring total body surface area (BSA) measurements and renal function measurements like glomerular filtration rate (GFR) can significantly reduce prescriber errors and lessen the time required to furnish a drug to a sick patient [3]. The electronic prescription accuracy verification procedures provide a safety bulwark against oversights from and miscommunications between health care professionals in different facilities or clinical silos as drug administration procedures and protocols can vary greatly even within organizations [8]. Collectively, these procedures generally function to homogenize and expedite healthcare delivery practices in large healthcare networks.

Use of a CPOE/CDSS, therefore, has great potential to improve the safety and quality of the chemotherapy preparation and treatment process.

2 Aim of the study

The aim of the present study is to evaluate whether the clinical use of a proprietary CPOE/CDSS called CenseoRx®

can enhance the safety of the chemotherapy-use process by reducing dosage medication errors and by expediting the chemotherapy patient intake process to facilitate a safer and higher quality of oncology care by pharmacists and doctors. This was done by observing and comparing the therapeutic dosing decisions of prescribing cancer physicians and the recommended dosing decisions of the CPOE/CDSS software system over the 1-month study period for the 58 probands. The results are presented as mean differences between the physician-prescribed and software-prescribed dose based on dosage calculation subtype. The time required to admit a new patient and the time required to log laboratory exams were recorded on the first and last week of the study period and compared.

3 Methods

3.1 Clinical Decision Support system

The CenseoRx® CPOE/CDSS was developed by clinical pharmacists in collaboration with a team of software engineers and designers based on peer-reviewed research and evidence-based protocols. This software program was created with the intention of improving cross-silo communication and treatment protocol adherence among physicians, pharmacists, and nurses in the provision of oncological care. Throughout the software design process, physician guidance and feedback were incorporated in the software interface and functionality to ensure compatibility with standard hospital workflow. CenseoRx® is a CPOE conjoined with a basic CDSS (CPOE/CDSS) and can be navigated by most healthcare professionals with basic computer skills.

The program features four core components: Calendar, Patients, Pharmacy, and Settings. Access and procedure modification rights are granted depending on the healthcare professional user, their specialty, and their attendant right to access patient data. Only users accorded CPOE/CDSS administrator rights can access all patient data sections on medication regimens and lab results and update the database accordingly. The CPOE/CDSS holds all relevant information regarding the therapeutic protocols, the tumor location, and the dosage adjustments. The programmatic therapeutic protocols generated by CenseoRx® are automatically updated from current National Comprehensive Cancer Network and Hellenic Society of Medical Oncology guidelines. Pursuant to these protocols, the program contains additional information regarding the medicines, drug categories, medicinal products, pharmaceutical forms, pharmaceutical companies, package types, and administration routes relevant to each chemotherapy patient file. Pharmaceutical intervention suggestions are generated by the CPOE/CDSS according to

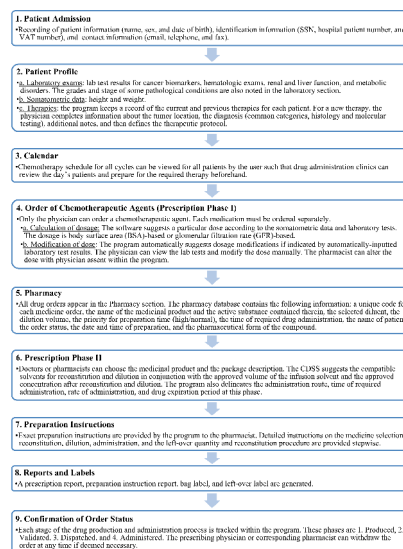


Fig. 1 A brief overview of chemotherapy treatment process when using the CenseoRx® CDSS/CPOE software for clinical practice

data on the “Summary of Product Characteristics” for each administered drug. CenseoRx® also contains patient files on laboratory test results germane to cancer treatment and the corresponding diagnosis and indication. Figure 1 provides an illustrated overview of the chemotherapy treatment process when using the CenseoRx® CDSS/CPOE software in clinical practice. For comparison, Fig. 2 provides an illustrated overview of the chemotherapy treatment process at IASO Hospital in Athens, Greece in the absence of clinical integration of an order entry and decision support software system.

3.2 Study design and patients

To evaluate whether the clinical use of the CenseoRx® CPOE/CDSS enhances the safety of the chemotherapy-use process by reducing dosage medication errors and by expediting the chemotherapy patient intake process, we conducted a pilot implementation of the CPOE/CDSS. Study recruitment took place at IASO Hospital in Athens, Greece during a 1-month period. Over the course of the observational period, the 58 study patients were diagnosed with cancers of the breast, colon, ovarian, endometrial cervical, prostate and neck. Other study patients were also diagnosed with non-small cell lung cancer, pancreatic adenocarcinoma, and uterine sarcoma. Patient weight, height, age, cancer type, and therapeutic protocol were recorded and required for study inclusion; for patients prescribed medications with AUC-based dosing and GFR-based dosing schedules, patient serum creatinine levels were recorded.

During the trial study, the therapeutic choices of the physicians and the automated choices of the CPOE/CDSS

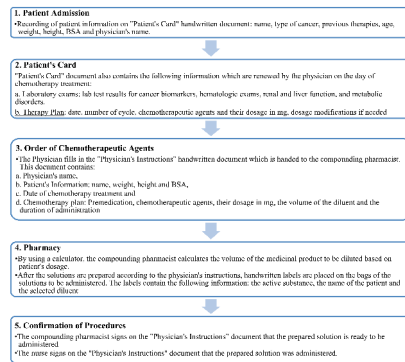


Fig. 2 A brief overview of chemotherapy treatment process at IASO Hospital without using the CenseoRx® CDSS/CPOE software

were compared for each prescribed chemotherapeutic protocol, specifically the physician-prescribed dose and CPOE/CDSS-calculated dosage via a post hoc dosage calculation. Patients were treated with the physician-prescribed chemotherapeutic dose and treatment intervention did not occur. Several chemotherapeutic agents are prescribed on a fixed-dosing regimen and were thusly excluded from the comparative analysis; fixed-dose drugs excluded from this analysis were Pertuzumab, Trastuzumab (by subcutaneous injection), Pembrolizumab, Nivolumab and Zoledronic acid [10]. As a result, only chemotherapeutic agents with body surface area (BSA)-based dosing, area under the curve (AUC)-based dosing, or weight-based dosing were included in the statistical comparative analysis.

In addition, we investigated the time required to admit a new patient and to log patient laboratory exams over the course of the 1-month study period to gauge healthcare

Table 1 Patient characteristics and demographic data

Characteristics	n = 58
Sex (male/ female)	8/50
Age (years)	57.45 ± 13.56
BSA (m ²)	1.735 ± 0.147
Types of Cancer, n (%)	
Breast cancer	40 (68.96%)
Ovarian Cancer	4 (6.90%)
Non-Small Cell Lung Cancer	3 (5.17%)
Colon Cancer	5 (8.62%)
Endometrial Cancer	1 (1.72%)
Cervical Cancer	1 (1.72%)
Head & Neck cancer	1 (1.72%)
Pancreatic Adenocarcinoma	1 (1.72%)
Uterine Sarcoma	1 (1.72%)
Prostate cancer	1 (1.72%)
Number of drugs per patient, n (%)	
1	26 (44.83%)
2	14 (24.14%)
3	11 (18.96%)
> 4	7 (12.07%)

provider inurement to the CPOE/CDSS software. With respect to admission time, we recorded the patient first name, last name, sex, birth date, height, weight, therapy start date, tumor location, protocol, and attendant doctor. With respect to laboratory exam log time, only patients which met the threshold of having received lab tests for serum hemato-crit, hemoglobin, white blood cell count (WBC), platelet count, absolute neutrophil count (ANC), glucose, lactate dehydrogenase (LDH), urea, creatinine, bilirubin total, aspartate aminotransferase (AST), alanine aminotransferase (ALT), alkaline phosphatase, gamma-glutamyl transferase (GGT), and cancer biomarker tests for CA125, CA19-9, CA15-3 and CEA were included in the time comparison for commensurability.

Descriptive and statistical analyses were carried out with IBM SPSS Statistics 26 and Graph Pad Prism 9. For the comparative analysis between the software-calculated doses and the doctor-prescribed dose, we performed a paired two sample t-test for the chemotherapeutic agents that had a BSA-based dose. A Wilcoxon non-parametric rank test for paired samples was performed for the chemotherapeutic agents that had AUC-based or weight-based dosing, as collected data did not meet the normal distribution criteria. A p-value of < 0.05 was considered significant.

4 Results

Data from 58 individuals (50 female and 8 male patients) were recorded. General patient characteristics and demographic data are presented in Table 1. Over the 1-month study trial period, these patients were administered an average of 2.12 +/- 0.97 different chemotherapeutic agents. Overall, 127 administered chemotherapeutic agents were administered and examined during our intervention. Of the 127 administered and compared chemotherapeutic agents, 30 had a fixed dose. A total of 97 administered chemotherapeutic agents with BSA-based, AUC-based, or weigh-based dosing were analyzed. A significant difference between the doctor-prescribed and the CPOE/CDSS recommended dosage of the chemotherapeutic agents was observed for medications requiring mixed dosing (body surface area (BSA)-based dosing, area under the curve (AUC)-based dosing, or weight-based dosing) [mean difference = 18.42 mg chemotherapeutic agent, p = 0.004] and for medications requiring solely AUC-based dosing [mean difference = 95.62 mg chemotherapeutic agent, p = 0.0295], with doctors under-prescribing the chemotherapeutic as compared to the CPOE/CDSS in both dosing categories. As such, CPOE/CDSS-calculated dosages were more aligned with current National Comprehensive Cancer Network and Hellenic Society of Medical Oncology

guidelines for dosing than were the doctor-prescribed dosages (Table 2).

We also investigated healthcare provider habituation to the CPOE/CDSS software by measuring the time required for new patient admission on the first day and last week of the 1-month pilot intervention period. On the first day, the admission of 9 new patients in the CPOE/CDSS took a mean 229.5 ± 10.9 s. After three weeks of using the software, the admission of 9 comparable new patients took a mean 108 ± 12 s.

Similarly, we investigated the time required to log patient laboratory exams in the software program during the first day and the last week of the 1-month pilot intervention period. On the first day, the recording of laboratory exams for 6 patients took a mean 243 ± 7 s. After 3 weeks of using the software, the recording of laboratory exams for 6 comparable patients took a mean 154 ± 6 s.

5 Discussion

Our results indicate that the cancer physicians evaluated in this study consistently and systematically mis-dosed chemotherapeutic agents when AUC-based dosing or aggregate AUC-, BSA-, and weight-based dosing calculations were required. Though the present study is only powered to detect significant mean differences in physician-prescribed and software-calculated chemotherapeutic doses and not to draw robust conclusions about the clinical consequences of miscalculated chemotherapy dosing, previous work has demonstrated poor clinical outcomes with even minor mis-dosing of chemotherapeutic agents (Mattsson et al., 2015). For example, it is reasonable to assume that for a low weight patient the absolute difference of the prescribed dosage from the recommended dosage would be more clinically relevant than for a high weight patient. Further, dosage errors for cytotoxic agents will be more acute for all patients when they are a higher percentage of the total dose.

Though we observed no outright case of medication error in this study trial as reported in Mattsson et al., 2015 and as reported extensively in the literature, the significant

mean differences in doses prescribed between the physician and software observed in this research study are an alarming observation that warrants further study. Dosages for prescribed cytotoxic agents even minorly misaligned with up-to-date National Comprehensive Cancer Network and Hellenic Society of Medical Oncology guidelines may increase the risk for iatrogenic harm to patients and for sub-optimal treatment or even therapeutic failure.

If the external validity of this study is established by future research, the population-level implications are extensive. An estimated 9.8 million patients receive chemotherapy treatment each year [15]. Even if minor errors in the dosage calculation of cytotoxic drugs are unlikely to cause harm to a single proband, the risk of iatrogenic harm to a large swathe of patients is high if only a small percentage demonstrates a poor response to a minor mis-dosing.

In the paradigm of the current study, medication error risk reduction is therefore the primary benefit of clinical CPOE/CDSS use, as physician mis-dosing is one of the treatment phases most amenable to human error. The CPOE/CDSS used in the present study automatically calculates the cancer patient BSA, GFR, and concomitant dose of the prescribed chemotherapeutic agents with precision and accuracy. As a result, it hastens rote and calculation-intensive procedures to reduce clinicians' workload and potential for committing serious dosage medication errors.

Ancillary benefits include automatic protocol updates pursuant to the most recent prescribing guidelines and the elimination of clerical errors like prescription transmission delay or loss of printed prescription records. In the context of medical training, CPOE/CDSS integration can provide instructive dosing calculations and patient parameters for clinical consideration by both residents and attending physicians. As previously demonstrated, CPOE/CDSS software can collate patient data across large healthcare networks, simulate real-life clinical scenarios, and enhance the exchange of clinically relevant data according to newly reported patient treatment outcome trends [9, 13]. Connectedly, CPOE/CDSS flexibility is another core asset. Protocol, dosage, and route of administration modifications allow for discretionary control by physicians while still providing a necessary software-assisted backstop to verify prescription

Table 2 Results of statistical analysis

Type of chemotherapy dosing	Number of administered chemotherapeutic agents	Mean value of dose (mg)		Mean difference (mg)	Sig. (2-tailed)
		Doctor	Software		
Fixed dose	30	445.600	445.600	0	-
Weight-based dose	12	749.208	731.667	17.541	0.3125
AUC-based dose	14	431.643	527.259	-95.616	0.0295
BSA-based dose	71	579.972	583.321	-3.349	0.1340
AUC, BSA or weight-based dose	97	577.330	595.752	-18.422	0.0040

safety and accuracy by categorizing all clinical information into intelligible and fixed formats.

Perhaps the most salient yet understudied benefit of CPOE/CDSS implementation is the cost-savings, a primary driver of adoption of clinical software solutions by health-care institutions. These cost-savings are principally derived from (1) the utilization of leftover medication as chemotherapeutic agents can be prohibitively expensive; (2) the gains in efficiency accompanying the modernization and streamlining of chemotherapeutic treatment delivery; and (3) the cost savings associated with averting costly medication errors [14]. Further research on the cost-savings benefits of CPOE/CDSS integration for both providers and society at large in the provision of chemotherapy is warranted.

6 Conclusions

The clinical implementation of the CenseoRx® CPOE/CDSS for chemotherapy treatment significantly reduced dosage medication errors and improved chemo-logistics and clinical practice for doctors and pharmacists. Generally, CPOE/CDSSs can enhance the safety and quality of a chemotherapy treatment protocol, from prescribing practice to the production of the pharmaceutical compound, while simultaneously generating cost-savings. Additionally, CPOE/CDSSs allow for an evidence-based electronic integration with clinical oncology practice and may improve patient response to chemotherapeutic interventions. As there are myriad applications of CPOE/CDSSs for improving clinical practice and patient outcomes beyond the narrow provision of chemotherapy treatment, future research on CPOE/CDSS integration with other domains of clinical practice is warranted.

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Author contributions P.P., G.P., and M.S. conceived the study, searched the literature, and secured IASO General participation in the research. S.K. searched and analyzed literature, prepared the tables/figures, and reviewed the manuscript. K.N. and J.S. analyzed the literature and wrote the manuscript. All authors have read and agreed to the published version of the manuscript.

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Data availability statement The dataset generated and analyzed during the current study are available from the corresponding author, J.S., on reasonable request.

Declarations

Competing interests Two of the study authors, P.P. and G.P., have financial ties to the CibusMed PC, the company that developed and owns the CenseoRx® CPOE/CDSS system. These authors did not bias

the study findings nor conclusion as verified by the three disinterested researchers. The remaining authors have no conflicts of interest to disclose.

Ethics approval The study protocol was approved the IASO General, Maternity and Gynecological Clinic Hospital's Scientific and Ethical Committee (Approval Code: 31052019).

The current study did not require patient consent nor approval by an ethics committee, as no intervention was involved, data were anonymized, and no patient identifying information was provided. All information regarding participants' clinical condition, medication, and medical history were provided anonymously by two prescribing clinicians; as such, no nexus between patient identity and treatment protocol nor indication was formed. Nevertheless, IRB approval for the study protocol was requested and granted by the IASO General, Maternity and Gynecological Clinic Hospital's Scientific and Ethical Committee (Approval # 31052019).

Consent to participate The current study did not require patient consent to participate as no intervention was involved, data were anonymized, and no patient-identifying information was provided. Thus, clinical equipoise considerations are not relevant. All information regarding participants' clinical condition, medication, and medical history were provided anonymously by two prescribing clinicians; as such, no nexus between patient identity and treatment protocol nor indication was formed.

Consent to publish Not applicable.

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